

INSTRUCTIONS FOR USE

Single-dose prefilled syringe

For subcutaneous use only.

40 USP units/0.5 mL and 80 USP units/mL

This Instructions for Use contains information on how to prepare and inject Purified Cortrophin Gel prefilled syringe.

Your healthcare provider should show you how to prepare and inject Purified Cortrophin Gel the right way before you inject it for the first time. Do not try to inject yourself until you have been shown the right way to give your injections by your healthcare provider.

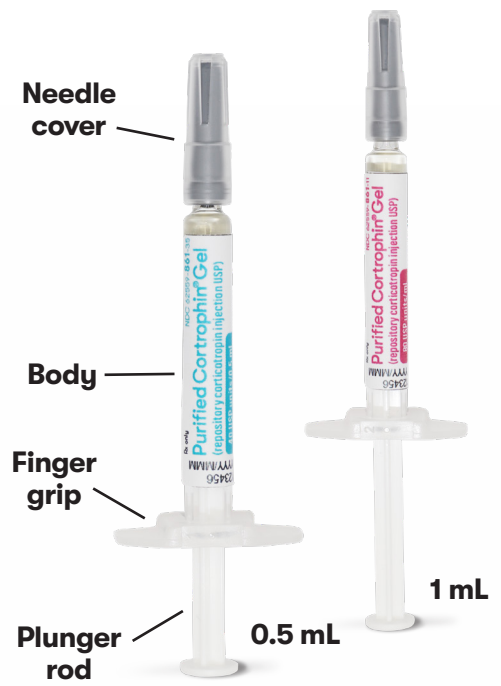


Figure A

Prefilled syringe sizes are not to scale.

Important information you need to know before injecting Purified Cortrophin Gel

- Read all of this Instructions for Use carefully before using the Purified Cortrophin Gel prefilled syringe.
- Purified Cortrophin Gel is given as an injection directly under the skin as directed by your healthcare provider.
 - **Do not** inject it into a vein or take by mouth.
- Inject Purified Cortrophin Gel exactly as your healthcare provider tells you. Your healthcare provider will tell you where to give the injection, how much to give, how often, and when to give it.
 - **You may need more than 1 injection based on your prescribed dose.**
- Do not use Purified Cortrophin Gel until your healthcare provider has shown you how to give the injection.
- Do not use if the tamper evident seal is torn, loose, or not present.
- Do not use the Purified Cortrophin Gel prefilled syringe if it has been dropped on a hard surface or damaged.

What is Purified Cortrophin Gel?

Purified Cortrophin Gel is a prescription medicine that is injected under the skin when administered using a prefilled syringe. It is used for:

- Short-term add-on therapy to help manage acute episodes or flares in rheumatoid arthritis, including juvenile rheumatoid arthritis; psoriatic arthritis; ankylosing spondylitis; and acute gouty arthritis.
- Treatment for flares or as maintenance therapy in select cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).
- Treatment for severe skin reactions (Stevens-Johnson syndrome) and severe psoriasis.
- Treatment for atopic dermatitis (eczema) and serum sickness.

Important Safety Information

DO NOT use Cortrophin Gel if you have any of the following conditions:

- A skin condition called scleroderma
- Bone density loss or osteoporosis

Please see additional Important Safety Information throughout and full [Prescribing Information](#) and [Instructions for Use](#).

STEP 1: Collect your supplies

- ▶ Use a clean, flat surface, such as a table.
- ▶ You will need (see **Figure B**):

Included in Carton	Additional Supplies Needed (Not Included in Carton)
1 Purified Cortrophin Gel prefilled syringe (see Figure A) 	1 Alcohol pad  1 Cotton ball or gauze pad  1 Bandage (if needed)  Sharps disposal container for throwing away used syringes and needles (see page 5 of this guide for “STEP 6: Disposing of your used prefilled syringes and needles”) 

Figure B

STEP 2: Preparing the prefilled syringe

- ▶ Remove the carton from the refrigerator and place on a clean surface for **45 minutes** to let the prefilled syringe warm up to room temperature 68°F to 77°F (20°C to 25°C) (see **Figure C**).
 - Purified Cortrophin Gel will be a solid gel when refrigerated, and it needs to be warmed to a liquid gel before injecting.
 - Remove the prefilled syringe by the syringe body only. **Do not** remove the prefilled syringe by the plunger rod or needle cover.
 - **Do not** remove the needle cover while allowing the prefilled syringe to reach room temperature.
 - **Do not** warm the prefilled syringe in any other way. For example, do not microwave or heat on the stove.
 - **Do not** use the prefilled syringe if the gel in the syringe still appears to be solid.



Figure C

What is Purified Cortrophin Gel? (continued)

- Treatment for severe acute and chronic allergic and inflammatory conditions affecting different parts of the eye. This can include the front part of the eye such as the cornea and iris, or the back part of the eye such as the optic nerve and retina.
- Treatment for people with symptoms of sarcoidosis.
- Reduction of protein in the urine of people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or due to lupus.
- Acute attacks or flares of multiple sclerosis.

Important Safety Information (continued)

DO NOT use Cortrophin Gel if you have any of the following conditions (continued):

- Fungal infections
- Ocular herpes simplex (an eye infection)

Please see additional Important Safety Information throughout and full **Prescribing Information** and **Instructions for Use**.



STEP 3: Check your medicine

- ▶ Check the expiration date on the syringe label (see **Figure D**). **Do not** use if expiration date has passed.
- ▶ Make sure that you have the right dose as prescribed to you by your healthcare provider. Your dose may require more than 1 injection.
- ▶ Check that the liquid gel in the syringe is light amber (yellow) in color. **Do not** use if the gel appears cloudy or has particles in it. Throw it away (discard), and get a new syringe.
- ▶ It is ready to be used when the medicine is a liquid gel and not a solid gel.

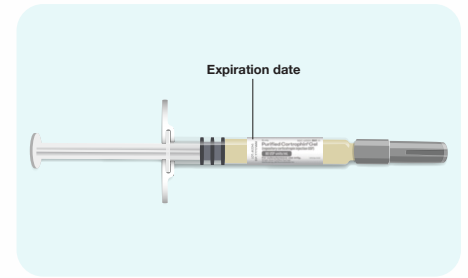


Figure D

STEP 4: Selecting an injection site

- ▶ Wash your hands well and dry with a clean towel.
- ▶ **Choose an injection site** on the stomach (abdomen) area or upper thigh (see **Figure E**).
 - **Do not** inject within 2 inches of the belly button (navel).
- ▶ **Do not** inject in areas where the skin is red, swollen, irritated, inflamed, tender, bruised, scaly, hard, or has scars or stretch marks.
- ▶ **If someone else is giving you the injection**, it can also be injected in the side and back of the upper arm (see **Figure F**).

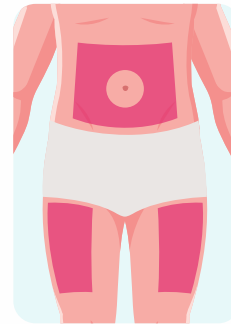


Figure E

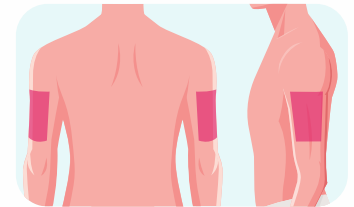


Figure F

Important Safety Information (continued)

DO NOT use Cortrophin Gel if you have any of the following conditions (continued):

- A recent surgery
- Stomach ulcers or a history of stomach ulcers
- Heart failure
- High blood pressure
- Allergies to pig-derived proteins
- Adrenal glands that do not make enough of the hormone cortisol (primary adrenocortical insufficiency) or
- An adrenal cortex that makes too much of the hormones cortisol and aldosterone (adrenocortical hyperfunction)

Tell your doctor if you:

- Have or have had any other health problems
- Are taking any prescription or over-the-counter medicines, including aspirin, vitamins, and herbal or dietary supplements

Please see additional Important Safety Information throughout and full [Prescribing Information](#) and [Instructions for Use](#).

STEP 5: Injecting Purified Cortrophin Gel

- ▶ Clean the injection site with an alcohol pad (see **Figure G**). Allow to air dry.
- ▶ Hold the syringe by the body with one hand.
 - **Do not** move or pull back on the plunger.
- ▶ Remove the needle cover with the other hand and throw it away (discard) (see **Figure H**).
 - **Do not** touch the needle.
 - **Do not** recap the needle.
 - You may see a drop of liquid at the end of the needle. This is normal.
- ▶ With one hand, gently pinch the area of the cleaned skin and hold it firmly (see **Figure I**).
- ▶ Insert the needle into the pinched skin at a 45-degree angle (see **Figure I**).
- ▶ Release the pinched skin and slowly push down the plunger until all the medicine has been injected.
- ▶ Pull the needle out of the skin while keeping the syringe at the same angle.
- ▶ There may be a small amount of blood at the injection site. You can press a cotton ball or gauze pad over the injection site. Do not rub the injection site.
- ▶ If needed, you may cover the injection site with a bandage (see **Figure J**).



Figure G

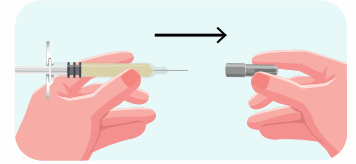


Figure H

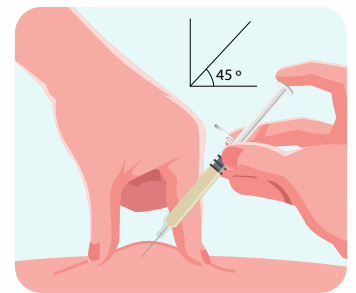


Figure I



Figure J

Important Safety Information (continued)

Tell your doctor if you (continued):

- Have any allergies
- Are about to receive any vaccine
- Are pregnant or plan to become pregnant. Cortrophin Gel may harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if Cortrophin Gel passes into your breast milk and if it can harm your baby.

What important information do I need to know about Cortrophin Gel?

Be sure to take Cortrophin Gel exactly as your doctor has directed. Always inject Cortrophin Gel under the skin or into the muscle. **Do not inject Cortrophin Gel directly into the vein.**

- You may be more likely to get infections. Contact your doctor at the first sign of an infection or fever.
- Your body may not produce enough natural cortisol after you stop taking Cortrophin Gel long term. This is called adrenal insufficiency. Your doctor may try to reduce your dosage gradually or prescribe a steroid medicine to protect you until the adrenal gland recovers.

Please see additional Important Safety Information throughout and full **Prescribing Information** and **Instructions for Use**.

STEP 6: Disposing of your used prefilled syringes and needles

- ▶ Throw away (discard) the prefilled syringe into an FDA-cleared sharps container right away after use (see **Figure K**). **Do not** throw away (dispose of) your used needles and syringe in your household trash.
- ▶ If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- ▶ When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- ▶ Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.



Figure K

Important Safety Information (continued)

What important information do I need to know about Cortrophin Gel? (continued)

- You might develop high blood pressure, retain too much salt and water, or have low blood potassium levels. As a result of this, your doctor may recommend some changes to your diet, such as eating less salt or taking certain supplements.
- Corticotropin therapy may hide symptoms of other diseases. This can make it more difficult for your doctor to make a diagnosis if something else is going on.
- Taking Cortrophin Gel can make you feel irritable or depressed. You may also have mood swings or trouble sleeping.
- You might develop certain eye conditions, such as cataracts, glaucoma, or optic nerve damage.
- You may develop allergies to Cortrophin Gel. These allergies may be severe. Signs of an allergic reaction include dizziness, nausea and vomiting, skin reactions (rash or itching), swelling of the face, tongue, lips or throat, and trouble breathing.
- The effects of Cortrophin Gel may be intensified if you have an underactive thyroid or cirrhosis of the liver.

Please see additional Important Safety Information throughout and full [Prescribing Information](#) and [Instructions for Use](#).

Storing Purified Cortrophin Gel prefilled syringes

- Store Purified Cortrophin Gel prefilled syringes in the carton provided in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Purified Cortrophin Gel prefilled syringes **may** be stored at room temperature between 68°F to 77°F (20°C to 25°C) **for up to 24 hours**.
- Keep Purified Cortrophin Gel prefilled syringes in the carton until ready to use.
- Throw away (discard) Purified Cortrophin Gel prefilled syringes right away after use or by the expiration date stamped on the syringe.
- **Keep Purified Cortrophin Gel and all medicines out of the reach of children.**

We're in your corner, every step of the way

Support that's designed to help you throughout the treatment process

Cortrophin
In Your
Corner™

Cortrophin In Your Corner is a dedicated program designed to support you and help you access treatment. Once you are prescribed Cortrophin Gel, the *Cortrophin In Your Corner* program* can provide you with support and educational information throughout your treatment.

*Not all patients will be eligible for all services offered by *Cortrophin In Your Corner*.



Questions? Please call
Cortrophin In Your Corner
at **1-800-805-5258**.

OR



For more information about
Cortrophin In Your Corner, visit
[Cortrophin.com/Support](https://www.cortrophin.com/Support) or
scan the QR code.

Important Safety Information (continued)

What important information do I need to know about Cortrophin Gel? (continued)

Side effects of Cortrophin Gel include fluid or salt retention; weight gain; muscle weakness; osteoporosis, stomach ulcers with possible bleeding; injection site reactions; impaired wound healing; high blood pressure; convulsions; headache; development of Cushingoid state (a hormonal condition often characterized by facial puffiness and weight gain); suppression of growth in children; and allergic reactions that may be severe.

These are not all of the possible side effects of Cortrophin Gel. Call your doctor or pharmacist for medical advice about side effects. You may report side effects to ANI Pharmaceuticals, Inc. at 1-800-308-6755 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout and full [Prescribing Information](#) and [Instructions for Use](#).



© Copyright 2025 ANI Pharmaceuticals, Inc. All Rights Reserved. Cortrophin is a registered trademark of ANI Pharmaceuticals, Inc. Cortrophin In Your Corner is a trademark of ANI Pharmaceuticals, Inc. All other trademarks are property of their respective owner. US-CG-2500060 09/25

 **Purified
Cortrophin® Gel**
repository corticotropin
injection USP 80U/mL